



WFCO
WFCC

**Committee on Postal,
Quarantine and Safety
Regulations Report
2000-2004**

**Postal, Quarantine and
Safety Regulations:
Activities, Developments
and Concerns**

WORLD
FEDERATION
FOR
CULTURE
COLLECTIONS



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**COMMITTEE ON POSTAL, QUARANTINE AND SAFETY
REGULATIONS
REPORT 2000-2004**

**POSTAL, QUARANTINE AND SAFETY REGULATIONS:
ACTIVITIES, DEVELOPMENTS AND CONCERNS**

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On behalf of the WFCC PQSR Committee
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Contents	page
Committee Members	2
1. The Work Plan 2000-2004	3
2. Summary	4
3. Overview on Main Activities and Milestones	4
4. Transport of Microorganisms	5
4.1 Introduction	5
4.2 Definitions	6
4.3 Questionnaires on Shipping Problems	7
4.3.1 Infectious Substances Shipping	7
4.3.2 Delivery by Postal Mail Services	8
4.4 UPU Developments	9
4.5 Irradiation of Air Freight consignments and Postal Letter Mail	9
5. UN Negotiations on Transport Deregulations	10
6. Bioterrorism and Biosecurity Issues	12
7. Development of Information Resources	16
8. Quarantine Regulations : a Topic for BRCs	16
9. News from the Countries and Regions and other News	20
10. Areas of Concern for Future Activities	21
Acknowledgements	
Useful References	
Appendix	
Proposal by the WFCC, World Federation for Culture Collections	
Committee on Postal, Quarantine and Safety Regulations	
Informal Paper Revisions to ST/SG/AC.10/C.3/2004/51	

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1. The Work Plan 2000 - 2004

1. Considering expanding the scope of this Committee to attend to microbial toxins and, as one consequence, to the restrictions placed by the Australia Group (biological war weapons). Is an international harmonization with respect to the problem of "select agents" possible? Comparison of and closer look at the different regional or national regulations should be done. In the near future, the Australia Group will meet and discuss a possibly easier access to kits of organisms which are affected. The Committee should have a closer look at the resp. lists of organisms.
2. The Committee should try to work towards a different hazard classification for transport and handling (intended use) or at least, work towards easier packaging and shipping procedures from the practical point of view. On the other hand, without doubt the user's knowledge and willingness regarding responsibility has to be strengthened. This can be done by distributing information material or publications, information sheets, lists with national manufacturers of packaging systems etc.
3. Working towards establishment of job-specific dangerous goods ICAO/IATA training courses in the different countries (on national level) would increase the willingness of the shippers to accept regulations and to handle their shipments correctly.
4. Committee members should try to establish or to keep good contacts to their national/regional authorities in order to reach a level of collaboration.
5. The same importance has to be realised with respect to the contacts with the scientific community. A feedback can only be expected when there are efforts before. Committee members should try to gain more information from scientists.
6. Working on the question: how is administration with respect to safety data management and safety paperwork performed at the different cultures collections? This deals with those strains which are affected by different kinds of restrictions. Which kinds of written information are accompanying a shipment of cultures (e.g. safety data sheets)?
7. Consider the opportunity of expanding the scope of the Committee to encompass ethics (related to human cell line distribution).
8. The existence of the Convention on Biological Diversity has to be kept in mind.

Goals which evolved during the past period of the Committee and which still need further attention

- * An improved more efficient way of gathering and distributing quarantine, safety and shipping data world-wide.
- * The WFCC needs to take a more active role in the development stages of new relevant legislation.
- * A restatement of the remit for the WFCC Committee on Postal, Quarantine and Safety Regulations and procedures is required that will give most benefit to WFCC members.
- * The production of safety standards for Microbial Resource Collections would be a useful step to take. It would be in keeping with other guidelines produced by the WFCC and would help set acceptable standards to be attained by collections worldwide (especially helpful for developing collections).
- * Compilation of information on microbial toxins, their production, containment, safe handling and hazard status and providing data to the recipients of toxin producers.
- * The Committee could provide more accurate data for future revisions of hazard lists of microorganisms, especially regarding the uncritical basis of determination and inclusion into higher Risk Groups.

2. Summary

The WFCC Postal, Quarantine and Safety Regulations (PQSR) Committee looks back to almost 30 years of existence: WFCC Newsletter No. 1, March 1975, announced the establishment of a Committee on Postal and Quarantine Regulations having the aim to collect and disseminate information on the relevant regulations. This demonstrates that even in the *pre* gene technology era, at times when bioterrorism was not a catchword, when dangerous goods shipping questions were not dominating daily life in the shipping departments of the Culture Collections and when biosafety and biosecurity did not receive as much attention as nowadays there was a demand to have a group among WFCC looking closer at the regulations. Scientists had to become familiar with all the regulations governing handling and distributing of biological materials. Over the years, the name of this Committee slightly changed, the list of the Committee members grew and so did the list of aims and goals. As for other WFCC Committees, it is of high relevance to have enough members who are working at Culture Collections/Biological Resource Centres in different regions all over the world. Actually, the PQSR Committee has twelve members in eleven countries. During the last term of office the achievement of some milestones needed a lot of attention. The most outstanding one was receiving observer status to the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) and the succeeding negotiations on shipping deregulations for Risk Group 2 cultures. The expectations regarding the latter had been very high.

The bioterroristic anthrax attacks with all the consequences like e.g. irradiation of freight consignments and letters and discussions have constantly occupied this Committee since September 2001. Bio-legislation covers a complex area of laws, regulations and guidelines on the international and national levels so that the PQSR Committee is necessarily characterised by vital correspondence and exchange of news. Its self-image and main mission is to function as a mirror reflecting the demands and problems of the Culture Collections on the one hand and of the world-wide scientific community on the other hand. In order to get more publicity and to demonstrate which issues are addressed by the PQSR Committee, a special flyer was published in August 2002 and widely distributed. The work of the Committee has by no means come to a final point but, needless to mention, there are open questions requiring a closer look. This WFCC Committee has been exciting since its foundation and has many challenges ahead of it.

3. Overview on Main Activities and Milestones

The PQSR Committee was able to fill many issues of its Work Plan successfully with life, some deserve more or constant attention in the future and some certainly beyond measure like e.g. world-wide biosecurity aspects (despatch of dangerous microorganisms/ " select agents " / " dual-use " material). A milestone to be highlighted was receiving the WFCC observer status to UNSCETDG and the succeeding positive negotiations on deregulating transport requirements for cultures of Risk Group 2. In order to receive more attention, the PQSR Committee produced a multi-colour flyer describing the main activities, aims and goals and containing the member addresses as well as the WFCC homepage access. Large numbers of this flyer were distributed by the PQSR members on different occasions, at the UN, BTWC Expert Meeting on Disarmament, Geneva, August 2003 and at the UNSCETDG Meeting in Geneva, July 2004.

4. Transport of Microorganisms

4.1 Introduction

Different kinds of biological materials/living cultures are supplied by Culture Collections and are travelling around the world. Progress in science and application, infectious diseases research and better control involves the respective test strains and it is essential that authentic cultures are supplied by recognised Culture Collections/Biological Resource Centres to recipients who are authorised to work with them. It is the mission to guarantee a supply worldwide if all precautionary steps have been taken before shipment so that cultures cannot fall into wrong hands. In between the shipper and the recipient of a microorganism is the **transportation chain** which has to work in a smooth and safe manner. In this context, those living (micro-) organisms have to be addressed that definitely or possibly bear the risk of either being infectious to humans or animals, being toxin producers or capable to alter other organisms in the environment (certain kinds of genetically modified microorganisms; see 4.2, Definitions).

In terms of international packaging and shipping regulations (**UN Model Regulations**), also microorganisms of Risk Group 2 have been defined as **dangerous goods** and have to be handled as such since many years. The respective packaging and transport regulations still fully apply until the official deregulation achieved by the WFCC PQSR Committee will be in force. Correct packaging and shipping requires a lot of care and sound knowledge on the complex regulatory background. A comprehensive information resource document for shippers, especially for those working at Collections, has been compiled by D. Smith and C. Rohde and is one of several documents produced by the European EBRCN project (www.ebrcn.org). Over the past decade, Culture Collections/BRCs have observed that quarantine, postal and packaging regulations become more rigorous the more they are ignored. However, it is a significant difference between working with a microorganism in a laboratory and handling a consignment containing a consciously and safely packed microorganism. Considering carefully all good reasons to work towards a sensible deregulation of the shipping regulations, the PQSR Committee has finally been successful and received positive feedback during the negotiations at the United Nations Experts meeting in July 2004 (see 5., UN Negotiations on Transport Deregulations and Appendix)

Among other arguments, the **definition of the Risk Group 2** *per se* necessarily led to a convincing standpoint as represented by PQSR at the UN; see Appendix Informal Paper Revisions: in this document we decided to compile the slightly different wordings of the definitions of the Risk Group 2 descriptions by the EU, NIH, Canadian Guidelines, CDC and WHO. Until now, the Risk Group definitions had been considered as the only possible basis to define the hazards of microorganisms during transport and consequently led to a clear classification: there are biological substances which are **dangerous goods** („dg“) (UN Class 6, Division 6.2) and such which are not regulated (not dangerous goods). It is fundamental for all shippers in all individual cases of shipments of biological materials to be certain about the dangerous goods status. This system has now been modified for diagnostic specimens (IATA Dangerous Goods Regulations 45th ed., 2004) but still applies in case of the „cultured microorganisms“ that have gone through a laboratory process in order to produce a pure culture. The allocation of organisms to the Risk Groups can slightly vary from country to

country or from region to region (e.g. Europe and USA) and is not harmonised on a world-wide basis, due to different health standards, precautionary methods (vaccination), climatic conditions and other aspects. This makes obvious that international transport of infectious substances sometimes bears a difficulty for the shippers. However, the PQSR Committee felt its mission to offer expertise and advice and to help make the regulations more realistic. Independently of the allocation of a “culture” to Risk Group 2 or to the new transport Category B, dramatically different shipping regulations that are solely dependent on the purpose why a culture is sent seemed no longer justified. It is advisable to read the resp. chapter in this report and the new Appendix I, Infectious Substances, of the IATA DGR 2004. For detailed information, see Appendix.

The “regulatory cascade” is headed by the United Nations Sub-Committee of Experts for the Transport of Dangerous Goods (UNSCETDG). All modes of transport (road, rail, air, sea, waterways) have to implement the **UN Model Regulations** (“Orange Book”). Of course, air transport plays an absolutely outstanding role for Culture Collections. ICAO is the next following International Authority (**ICAO Technical Instructions**), followed by **IATA** with the **Dangerous Goods Regulations** being the manual and practical guide for shippers. A typical triple packaging system resembling an UN-certified combination packaging for Division 6.2 microorganisms is required. This guarantees very high safety being the only barrier between the material inside and the person handling the consignment. Such packagings are commercially available through world-wide distributors. The specialised market has grown remarkably.

Culture Collections/BRCs are often asked for help in terms of „Step-by-step shipping instructions“. We have observed that colleagues outside Culture Collections/BRCs have no idea of the existence of strict and detailed transport regulations. However, the general or „job-specific“ training courses cannot be replaced by instructions or books. The IATA DGR are constantly updated (annual editions) and shippers are required to refresh their knowledge every second year if they are transporting dg by air. The awareness of correct transport of biological materials has only quite slowly come into being. Certainly, all institutions sending out infectious substances should be on the safe side as penalties can be very high even if there has been no transport accident (packaging damage) but an incident report only.

4.2 Definitions

Non-infectious Biological Substances

are substances containing viable microorganisms known not causing any disease in humans or animals. Organisms assigned to Risk Group 1 may be considered as non-infectious. They do not fall under any dangerous goods transport regulations. However, other restrictions may apply and certain packaging and shipping rules have to be followed. See “International Shipping Regulations” (note: plant pathogenic microorganisms do not fall under DG transport regulations, but they of course may fall under quarantine or other import restrictions).

Dangerous Goods

are substances or articles capable of posing a risk to health, safety, property or environment while they are transported by surface carriers or air. Dangerous goods are allocated to one of 9 Classes and to a specific UN number.

Infectious Substances

are substances known to contain, or reasonably expected to contain, pathogens. Pathogens are microorganisms (including bacteria, viruses, rickettsiae, fungi) or recombinant microorganisms that are known or reasonably expected to cause infectious disease in humans or animals. Organisms grouped with Risk Group 2, 3 or 4 are infectious substances and transport regulations for DG fully apply.

Genetically Modified Microorganisms

refers to organisms in which the genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. For the purpose of international transport regulations, such organisms are divided into the following categories:

- (a) genetically modified microorganisms meeting the definition of an infectious substance must be classified in DG Class 6, Division 6.2 and assigned UN 2814 or UN 2900; this means the fact of being an infectious substance has priority over the fact of being genetically modified.
- (b) animals which contain, or are contaminated with, genetically modified microorganisms meeting the definition of an infectious substance must not be transported by air unless exempted by the States concerned;
- (c) genetically modified microorganisms known or suspected to be dangerous to humans, animals or the environment must not be transported by air unless exempted by the States concerned (note: examples may be microorganisms carrying amplified toxin production properties);
- (d) except when authorised for unconditional use by the States of origin, transit and destination, genetically modified microorganisms not meeting the definition of infectious substances but being capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction must be classified in Class 9, Miscellaneous Dangerous Goods, UN 3245 (note: examples may be self-transmissible genetically engineered plasmids);
- (e) genetically modified microorganisms and organisms not meeting the definition of an infectious substance and not otherwise included above are not subject to the provisions (they are not regulated as DG; author's note: examples may be non-pathogenic bacterial hosts carrying "safety" cloning vectors).

4.3 Questionnaires on Shipping Problems

4.3.1 Infectious Substances Shipping

With respect to the survey/questionnaire sent around in November 2002, 17 responses from WFCC members (12 countries: Australia, Belgium, Brazil, Bulgaria, Canada, Czech Rep., Netherlands, New Zealand, Spain, Sweden, United Kingdom, USA) had been received. The aim was to get information and feedback for the German delegate to the UN Subcommittee of Experts for the Transport of Dangerous Goods (UNSCETDG). He offered to present the topic again during the December 2002 Meeting in Geneva, but only on the premises to have such information because the first attempt in July had not been successful for the classified organisms, whereas the UN Model Regulations already implemented a deregulation for diagnostic specimens. To summarise the results of this questionnaire:

Questions were

1. How is the intranational transport of low risk pathogens (RG 2) regulated in your country? Postal mail permitted? Differentiation between RG 2 and 3/4?
2. Are the RG 2 cultures you receive packed and shipped acc. to all the regulations?
3. Are most of your research partners/customers satisfied with the packaging and shipping regulations governing the transport of RG 2 or do you receive many questions and complaints?

Answers in summary were

1. Postal mail almost exclusively forbidden in the countries for RG 2, 3 and 4. No differentiations between RG 2 and 3/4. But, Canada has a differentiation between RG 2 and 3/4: RG 2 can be sent within Canada as dg exempt, but with the exception of 9 organisms which are fully regulated as dg. Canada forbids postal transport. Netherlands are working on permission of postal transport of RG 2. Germany has just forbidden it in August 2002.
2. Culture Collections are shipping correctly, many others not. Arriving cultures mostly packed o.k. in Canada and Spain. Experiences in all other countries are negative.
3. Many complaints: dg air freight too expensive, even "exorbitant" (up to approximately 100fold in costs compared to ordinary postal mail), this was the main complaint. Meanwhile, dangerous goods freight checks at some airports cost 130 €(TNT information, July 2004). Sometimes, shipments cannot be performed because of the costs. Too complicated also with too much paperwork. Not enough carriers available. Requirements are regarded as "over the top", correct packaging in UN packages should be safe enough. The costs of shipping dg impedes interchange of materials between scientists. International shipping of dg to Australia often possible only as airport to airport - far away from ideal situation! It has also been observed that obviously people (shippers) don't care that much anymore. Sweden is afraid of loosing the possibility to send RG 2 by postal service. No carrier as alternative in Sweden and Norway. Carriers often transport airport to airport only, not to the final destination. Some transports involve two carriers! Some carriers are very selective with the countries. Carriers often accept approved customers only.

4.3.2 Delivery by Postal Mail Services

In 2003, a questionnaire was sent around among the PQSR Committee membership regarding possible problems when living active cultures (**Risk Group 1**) are sent by international postal mail as in some regions mail delivery problems have been reported. We wanted to find out whether this might be due to difficult regional or national infrastructure. Such problems lead to customer reclamations and should of course be minimised where possible, at least in case of valuable actively growing cultures that have to be revived in the laboratory before shipping and/or in case of mail containing more than one culture. The result of the questionnaire was that in very rare cases such problems have been experienced by the Culture Collections and that **registered mail** offers a better guarantee on delivery. However, according to the Universal Postal Union, "perishable biological substances" (formerly "NPBS") should be sent as registered mail anyway. Tracking **must** be possible in case infectious substances are permitted in postal mail (registered mail system). Historically, postal services have always tried to perform expeditious, safe and cheap transport, but this all is possible only to a certain extent. An important difference between Postal mail and courier services is that in the latter case a freight consignment is treated individually by hand, making possible a better control on its destiny.

4.4 UPU Developments

National Post Offices are internationally linked together in the Universal Postal Union (UPU, Berne, Switzerland). UPU constantly updates the Letter Post Compendium, one of the Universal Postal Convention Acts (last revision at Beijing, 1999, next congress to be held in Bucharest in 2004). The Convention describes detailed regulations for the conditions of acceptance and marking of items containing *Perishable Biological Substances* (formerly called “NPBS, Non-infectious, Perishable Biological Substances”) and *Infectious Materials* (formerly called “IPBS, Infectious Perishable Biological Substances”). The relevant UPU Articles are RE 412 and RE 413, respectively and Article RE 207 for special packing requirements. C. Rohde is keeping up-to-date a countries list according to the UPU updates containing the most recent information on postal services for biological substances, their permit regarding receipt and dispatch by all national postal Authorities world-wide (UPU member countries). These UPU updates clearly demonstrate evidence for stricter tendencies. Cultures have always been seen as items causing disgust or aversion while they are shipped whereas the proverbially mentioned “broken blood samples” caused the true severe problems. Cultures of Risk Group 2 or higher are classified as dangerous goods being excluded from air mail and very often also from surface mail. However, acceptance of Risk Group 2 in UN-certified combination packagings in surface mail within the borders of a country has been a very appropriate possibility. This was permitted e.g. in Germany but withdrawn in August 2002.

4.5 Irradiation of Air Freight Consignments and Postal Letter Mail

Analytical Irradiation of Air Freight Consignments

DSMZ requested information from TNT concerning possible irradiation of air freight consignments for analytical detection purposes and received the following detailed response (November 2003): **all** air freight packages are checked by irradiation (metal detection) before entering an aircraft by applying a maximum of 1.6 microSv which is approximately comparable to 10% of the medically used X-ray dose. We know from customers reports and photographs that the consignments are carrying a large, self-adhesive seal-like yellow/black label after passing irradiation.

Inactivating Irradiation

The following information was written and its distribution via the WFCC web-site suggested by the PQSR Committee in April 2002 after consulting and seeking information exchange with American WFCC members and the German-American Chamber of Commerce Inc.:

WFCC received information that irradiation facilities have been/are to be installed by the US Postal Service at some locations in the USA in order to minimise possible bioterroristic attacks. Senders of biological material using the postal mail should therefore be aware of possible risks due to random or routine irradiation of their biological material when in transit. Harmless biological material which does not present a hazard for humans, animals or the environment (see WHO definition of Risk Group 1) is permitted in letter post by most of the national Postal Authorities world-wide as laid down by the Universal Postal Union (UPU). In order to prevent or minimise destruction or mutational alterations of such biological material and hence losses for scientific research and economy, senders should make advance arrangements as follows, these are recommendations by the WFCC:

- Documentation: The sender should attach a complete and clear list of contents to the consignment including the scientific name(s) of the organisms sent.
- Sender's bonafide declaration: The sender should clearly state (at least on the green customs label) that the organisms enclosed are harmless and NOT regulated as Dangerous Goods.
- Warning: A sticker with the wording "Please don't irradiate, harmless biological samples/cultures/microorganisms" or similar should be affixed to the mail.
- If the destination is close or within a governmental area/district, the sender should make advance arrangements with the consignee or consider to use a private courier service.

(further information on this topic: http://www.si.edu/scmre/mail_irradiation.htm/html)

5. UN Negotiations on Transport Deregulations

WFCC's Observer Status to the United Nations Economic and Social Council's Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG)

One year after the first official WFCC PQSR proposal on a deregulation of transport regulations for Risk Group 2 organisms had been offered to UNSCETDG in Geneva in June 2002, WFCC Secretary David Smith applied for WFCC observer status. The observer status was granted in summer 2003 and enabled WFCC to attend UNSCETDG Meetings (two per year), to be actively involved in discussions at the highest official level and to submit own documents and proposals to UNSCETDG, an active input to the **UN Model Regulations** ("Orange Book").

The following announcement was published by WFCC via <http://www.wfcc.info/wouep.html> in summer 2003:

(see next page)

The WFCC is granted Observer Status to the United Nations Economic and Social Council's Sub-Committee of Experts on the Transport of Dangerous Goods

To support the activity of the Postal, Quarantine and Safety Regulations the WFCC has recently been granted observer status to the United Nations Economic and Social Council's Sub-Committee of Experts on the Transport of Dangerous Goods. The WFCC secretariat presented data and background on the organisation and confirmed its interest in the goals and objectives of the Sub-Committee of Experts.

The Sub Committee works on global harmonization regarding criteria for health hazards and hazards to the environment, and it is co-operating with the International Labour Office, the World Health Organization, the United Nations Environment Programme and the Organisation for Economic Co-operation. In addition it has a role in the protection of workers, consumers and the general environment, in collaboration with experts. The Committee of Experts participates actively in relevant activities associated with the implementation of Agenda 21, and co-operates with international bodies involved in activities related to the transport of dangerous goods. Recent activities of the Sub Committee have resulted in changes to the 2003 IATA Dangerous Goods Regulations regarding diagnostic specimens.

The WFCC believes that it can provide relevant background information to the committee with regard to safe transport of potentially dangerous biological material. It could also act as a conduit for the recommendations and information back to the practitioners in the field. The WFCC would welcome the opportunity to offer its expertise regarding the safe handling and distribution of biological materials to the sub-committee. The WFCC already contributes to activities and information provision that help find collaborative solutions and procedures to facilitate compliance with regulations or that help define best practice. Its involvement with major international initiatives allows information flow for knowledge generation. Reports, publications, workshops, conferences and training courses provide the vehicles for information exchange and knowledge development.

One specific example where the WFCC could provide valuable input is providing a logical basis for the shipment of cultures of cells and micro-organisms where shipping regulations should be based on appropriate risk assessment. Observer Status will facilitate the WFCC to voice the opinions of members to the committee and will help the PQSR Committee achieve its goals.

A most outstanding milestone at the end of term of office has been achieved by the PQSR Committee: during the UN Experts meeting the proposal had a chance to be verbally presented. a sensible and realistic deregulation of the transport requirements for Risk Group 2 cultures. The proposal has been agreed and supported by other Nations or Organisations representatives including WHO. According to the agreements at the July 2004 Meeting of UNSCETDG, Geneva, such cultures will be transported like diagnostic specimens or cultures sent for diagnostic purposes if the definition of Category B applies. As a consequence, a new UN number as well as another Packing Instruction applies: UN 3373, PI 650. However, the agreements have to be set in force step-wise and the modified UN Model Regulations are first to be implemented by the Authorities for all transport systems/all modes of transport (air, road, rail, sea, waterways). ICAO, the International Civil Aviation Organization, has to implement the Model Regulations in their Technical Instructions before they are implemented by the IATA DGR. This final step will be by January 2007. Still, state and operator variations will be possible (DGR chapter 2, Limitations). The background of this development is very complex and it is recommended to read the detailed Appendix information.

6. Bioterrorism and Biosecurity Issues

The information provided in this Committee report is not comprehensive but serves to inform WFCC membership of the types of action being taken. The WFCC does not support a total ban on the supply of organisms that could be misused but requires its membership to adopt measures to prevent organisms falling into wrong hands. This topic became of serious concern following the terrorist threats in 2001 involving dangerous pathogens.

"BRCs should be in a position to provide accurate information on the variety of regulations for the shipment of specific biological resources and provide the guidance needed to achieve compliance with local, national and international regulations and ethical practices" (*Biological Resource Centres, Underpinning the Future of Life Sciences and Biotechnology*, OECD 2001, ISBN 92-64-18690-5). This reflects the tasks of the PQSR Committee: to observe international developments in the biolegislational sphere and to inform the WFCC members. BRCs have an intermediary position between access and despatch, between providers/depositors and users/recipients. Import/export regulations are mentioned as one of several distinct categories of the more fundamental restrictions, reflecting issues of principle and being rooted in laws. One of seven chapters of this valuable OECD publication (Chapter 5) deals with different restrictions affecting access. OECD states that there is insufficient international harmonisation of access restrictions, regulations, standards and practices. We can translate a part of Chapter 5 as being the basic goal of the PQSR Committee: "BRCs can play a major role in these efforts by providing the objective data and international comparisons upon which proposals for legal and regulatory harmonisation should be based."

Parts of the following text paragraphs have been taken from J. Swings et al. "*WFCC's Handling Bioterrorism Issues*", WFCC Newsletter 34, January 2002. This Newsletter was dedicated to the bioterrorism/bio-weaponry problem.

Safety issues related to pathogenic and dangerous organisms held in collections with regard to distribution of cultures to unauthorized or *malafide* third parties have occupied the WFCC for many years. In the month following the first reports about the anthrax attacks in the USA, the president of WFCC, like several other WFCC members, were contacted almost daily by different officials and the press (NYT, BBC, Reuters, NEC, Le Parisien, Le Monde...). In the international press, the idea prevailed that many countries have a lax legislation concerning the access to dangerous organisms, suggesting that the anthrax strains used in the attacks in the USA might have been obtained from WFCC member Culture Collections. However, there exist many other collections of microorganisms that are **not** registered with the WFCC. It is the purpose of this contribution (note: the original WFCC Newsletter 34 publication) to inform all WFCC members of the standpoint of WFCC with regard to dangerous organisms and of the actions taken or planned to tackle the above allegations.

Standpoint of the WFCC with regard to dangerous organisms

1. The WFCC supports the Biological and Toxin Weapons Convention of 1972 (BTWC) that prohibits the development, possession, and use of biological weapons.
2. It is not the policy of the WFCC to influence the range of biological resources maintained and to interfere with research activities of member collections. To the knowledge of the

WFCC no Culture Collection of its membership is involved in active research on biological weapons.

3. The control of access to dangerous organisms lies with the country in which the Collection is based. The national governments are the enforcers of international and national legislation. The WFCC urges its members to strictly follow all national and international legislations concerning distribution of sensitive materials to third parties. The WFCC requires its members to adopt best practice in performing their role in the conservation and utilisation of biodiversity, in compliance with such legislation. Indeed, the WFCC was the first organisation to compile an internationally approved set of guidelines covering all aspects of culture collection activity for its members (Guidelines for the Establishment and Operation of Collections of Cultures of Microorganisms, 1st edition 1990, 2nd edition 1999) (<http://wdcm.nig.ac.jp/>). In this context, sufficient and trained staff, knowledge, expertise and a well-functioning computerized shipping/export department are prerequisites for Culture Collections. One of the topics extensively treated in the Guidelines concerns the capability of Collections to meet all relevant national and international regulations concerning the control, transportation and health and safety aspects of resource handling and distribution. Several guidelines are devoted to aspects of liability, safe distribution of strains, data access and traceability, with explicit emphasis on strains which are potentially pathogenic to man, animals or plants (see Box below).

A rich information source for those deputies at BRCs who are responsible for export questions, is one of the EBRCN Information Resource Documents (www.ebrcn.org) compiled by Work Package 5 of this EU-funded project: “Controlled Distribution of Dangerous Microorganisms – The Control of Dual-use Goods” (see also 7.).

WFCC Guidelines relevant to bioterrorism issues

from: Guidelines for the Establishment and Operation of Collections of Microorganisms, 2nd edition 1999; <http://wdcn.nig.ac.jp>)

2.1 "The parent organization or board under which a service collection is established should be fully aware of and accept the responsibilities inherent in maintaining a public service to appropriate standards."

5.3 "If strains are maintained that are potentially pathogenic to man, animals or plants, or that produce toxic or hallucinogenic compounds, those holdings should be clearly labelled and kept secure. Adherence to safety and control regulations, whether institutional, national or international, is mandatory."

9.2 "Cultures listed as available in catalogues by service collections should normally be provided without restriction to those requesting them, subject to any international convention, import, quarantine or containment regulations that might apply."

9.4 "Cultures which for any reason, are not available for distribution should not be listed in catalogues or included in publicly accessible databases. Cultures with restricted distribution should be clearly marked."

9.5 "Strains which are pathogenic or toxic to plants, animals or man are generally subject to national or international regulations from health and/or agriculture authorities. Scientists requesting such strains may need to obtain permits to import material or to handle the cultures. Where cultures that are subject to such regulations are being supplied to a person or institution not known to the collection, written and signed guarantees must be obtained on the credentials of the person concerned and the containment facilities and expertise of the institution before dispatching cultures."

9.6 "Collections should maintain detailed records of recipients of cultures showing the material sent (with strain and batch numbers where appropriate), method and date of shipment, and name and address of the person to whom sent."

16.2 "Particular attention needs to be given to the containment and security aspects of strains which are potentially harmful to man, animals or crops."

The WFCC attempts to keep its members aware of national and international legislation with respect to Culture Collections. Its Committee on Postal, Quarantine and Safety Regulations recommended increased vigilance with respect to dangerous pathogens in its 1996 report (available on the WFCC pages of the WDCM website: <http://wdcn.nig.ac.jp/>), and this was extended in the annual report 2000 on the activities of this Committee. However, delivery of dangerous organisms had been one of the main topics of the PQSR Committee since years (see Committee report 1994-1996, printed WFCC publication by D. Smith). Organisms listed in the WDCM data bases are made available by the member Collections subject to the provision of relevant permits and licenses and released only to *bonafide* users in compliance with national and international legislation and conventions. The WFCC does not, and never has, controlled the distribution of cultures from these Collections.

Actions taken by the WFCC with regard to distribution of dangerous organisms

It was felt that WFCC had to take further steps to provide full and unambiguous information on its activities to officials, the press, its members and their customers, and all individuals interested in the activities of the WFCC. General actions were aimed at making the activities of WFCC more visible: a new WFCC flyer was produced and distributed to the Executive Board members and Committee chairs. A new domain name (www.wfcc.info) was acquired to enhance visibility and easier access to the web site.

With respect to the standpoint of WFCC on pathogenic agents, more specific actions were taken:

- * A first step was to obscure on the WFCC website any information on dangerous organisms in the member collections.

- * The topic was extensively discussed at the Executive Board meeting of the WFCC, held October 15, 2001, in Heraklion, Greece.

- * This discussion was continued thereafter by Email between several EB members and members of the Committee on Postal, Quarantine and Safety Regulations, and during an informal meeting in Hannover, December 13, 2001.

- * A statement was introduced on the web site of WDCM-WFCC with appropriate links to other web sites concerned with the matter.

Future actions

- * As a consequence of the acceptance of the principles of the Biological and Toxic Weapons Convention, the WFCC requires its members to control access to the dangerous organisms listed by the Australia Group as a minimum requirement. Half of the home countries of the member collections are indeed member of the Australia Group.

- * WFCC's PQSR Committee considers the comparison and harmonization of national legislations as a top priority. The recent events teach us that security will have to be tightened up even more, not only in culture collections, but in microbiological laboratories (private, university, state) in general. This will require consultations with IUMS, ASM and others in order to design a Code of Conduct. Contribution of the WFCC to such initiatives are needed.

It is the duty and responsibility of a professional organisation like WFCC, together with Colleagues microbiologists from all over the world and from other organisations to contribute to more security in the world. This needs surgical precision and should in no way hamper scientific research. The WFCC expects its members to adopt best practice in all its operations and the Guidelines it has provided and information generated from its committees aids this process.

Detailed information on the implementation of the Biological and Toxin Weapons Convention (BTWC), on the Australia Group and on several National measures has been compiled by D. Smith and C. Rohde in WFCC Newsletter 34. This publication provides background information including lists of organisms and web sites.

Of special concern are pathogens and toxins causing anthrax, botulism, brucellosis, plague, Q fever, tularemia and all agents classified for work at Biosafety Level 4 (Risk Group 4). In this context it is useful to bear in mind that we consider that the majority of exchange of all organisms is between individual scientists or research groups rather than through recognised Culture Collections.

7. Development of Information Resources

In order to harmonise standards and practice of implementation of laws and regulations at individual Culture Collections/BRCs, **EBRCN (European Biological Resource Centres Network)**, a project funded by the European Commission, focused on the development of helpful basic documents that can be used as exemplary working documents with the attitude to make BRC-internal implementation of relevant regulations easier. The documents were developed by Work Package 5 of this project, designed by D. Smith and C. Rohde who are contact persons if there are further questions. Wherever a BRC is located, independent of the size and whatever its main domains are: these documents cover almost all relevant aspects of bio-legislation and have high importance for all Culture Collections/BRCs to comply with:

EBRCN Information Resource Documents:

- Classification of microorganisms on the basis of hazard
- Quarantine regulations
- Ownership of intellectual property rights
- Convention on Biological Diversity (CBD)
- Safety information provided to the recipient of microorganisms
- Regulations governing packaging and shipping
- Control of distribution of possibly dangerous microorganisms
- Health and safety requirements

This list of existing information resource documents available via the EBRCN homepage www.ebrcn.org/ is perhaps not complete but offers a basis. The documents remain working documents that can be adapted to national legislation or adjusted to the Collection-specific requirements, biological resources and activities. By fulfilling this goal, the EBRCN project has worked as a nucleus for elaborating highly desired documents addressing many different issues concerned with daily life at Culture Collections/BRCs. The document dealing with **quarantine regulations** has been copied into this report under special heading as quarantine issues did not receive high priority by the PQSR Committee during the last years.

8. Quarantine Regulations: a Topic for BRCs

The PQSR Committee did not emphasise this issue so that its revival should be envisaged. However, as mentioned above, the European EBRCN project produced a number of helpful working documents on legal issues (D. Smith and C. Rohde), one of them is copied here:



EBRCN Information Resource Document

Quarantine Regulations

Quarantine legislation is in place in countries world wide restricting the import of non-indigenous plant and animal pathogens. Those who wish to import such organisms must hold the relevant import permit which can be obtained from the relevant country Authority. Information on the transport of plant pathogens throughout Europe can be obtained from the European and Mediterranean Plant Protection Organisation (EPPO), 1 rue le Nôtre, 75016 Paris, France (<http://www.eppo.org/>). The import and export of animal pathogens are similarly controlled and information can be found via the Office International des Epizooties (OIE) part of the World Organization for Animal Health 12, rue de Prony 75017 Paris, France (<http://www.oie.int>) Disease information is published in the OIE Bulletin every two months and the annual compilation is produced in *World Animal Health* ISSN: 1017-3102; ISBN: 92-9044-545-9

Receipt and Supply of Animal or Plant Pathogenic Organisms

BRCs must ensure that they are aware of the quarantine status of the organisms they accept into and store in their collections. The European Plant Protection Organisation provides lists of controlled organisms (see below) and individual countries may also have national lists. Non indigenous pathogens are not distributed by BRCs unless the recipient has a current licence from the relevant Authority to handle, store and use them. A BRC must hold copies of relevant legislation and all data records of strains held in the collection must state where there is a requirement for import or export permits. When delivering a plant or animal pathogen abroad a BRC must ensure that the recipient is aware that he is importing a potentially hazardous organism and that he has the relevant permits to do so. A BRC should where possible see copies of such permits where it is necessary that the material has to be accompanied by a permit.

Information on Plant Pathogens in Europe from the European Plant Protection Organisation

The European Plant Protection Organisation is an intergovernmental organization responsible for international cooperation in plant protection in the European and Mediterranean region. Under the International Plant Protection Convention, EPPO is the regional organization for Europe (<http://www.eppo.org/>).

EPPO's Objectives:

- EPPO protects plants
- Encourage harmonization of phytosanitary regulations and all other areas of official plant protection action
- Develop an international strategy against the introduction and spread of pests that damage cultivated and wild plants, in natural and agricultural ecosystems
- Promote the use of modern, safe, and effective pest control methods
- Provide a documentation service on plant protection

EPPO's Activities:

- Setting regional standards for phytosanitary measures and plant protection products
- Organizing Working Party and Panel meetings ([see EPPO meetings](#)) bringing together experts from all parts of the EPPO region
- EPPO is actively involved in [global activities related to phytosanitary measures](#) coordinated by the IPPC Secretariat within FAO.
- Organizing international conferences and workshops for plant protection researchers, managers of plant protection services, phytosanitary inspectors ...
- Publishing the journal *Bulletin OEPP/EPPO Bulletin*, the EPPO Reporting Service and the EPPO Summaries of Phytosanitary Regulations, providing an electronic documentation service, distributing database systems

EPPO Quarantine information is available at:

<http://www.eppo.org/QUARANTINE/quarantine.html>

The activities of EPPO concern any aspect of plant protection in agriculture, forestry and horticulture with an international dimension, in which National Plant protection Organizations are involved. An important part of these activities is plant quarantine, as one of the aims of EPPO is to prevent entry or spread of dangerous pests.

- Information on quarantine pests (A1 & A2 lists, data sheets, maps)
- Pest Risk Analysis
- EPPO Alert List
- Phytosanitary regulations
- EPPO Project on quarantine pests for forestry
- List of biological control agents widely used in the EPPO region
- Definitions in plant quarantine

Data Sheets on Quarantine Pests

The pests of the A1 and A2 lists (and EU annexes) are all covered by data sheets which give information on their host plants, geographical distribution, biology, economic importance, phytosanitary risk etc.

[http://www.eppo.org/QUARANTINE/Data sheets/datasheets.html](http://www.eppo.org/QUARANTINE/Data%20sheets/datasheets.html)

The International Plant Protection Convention:

<http://www.ippc.int/servlet/CDSServlet?status=ND0xMzI5MiY3PWVuJjYxPSomNjU9aW5mbw%7E%7E>

Information on Animal Pathogens:

The Office International des Epizooties (OIE), part of the World Organization for Animal Health

The Office International des Epizooties (OIE) is an intergovernmental organisation created by the International Agreement of 25 January 1924, signed by 28 countries. In May 2002, the OIE totalled 162 Member Countries.

Each Member Country undertakes to report the animal diseases that it detects on its territory. The OIE then disseminates the information to other countries which can take the necessary preventive action. This information also includes diseases transmissible to humans. Information is sent out immediately or periodically depending on the seriousness of the

disease. Dissemination is via the OIE Web site, e-mail and the following periodicals: Disease Information, published weekly, the OIE Bulletin published every two months and the annual compilation *World Animal Health*. The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from diseases, without setting up unjustified sanitary barriers. The main normative works produced by the OIE are: the International Animal Health Code, the Manual of Standards for Diagnostic Tests and Vaccines, the International Aquatic Animal Health Code and the Diagnostic Manual for Aquatic Animal Diseases.

Examples/Example Procedures

Clients in the UK who wish to obtain cultures of non-indigenous plant pathogens must first obtain a Ministry of Agriculture Fisheries and Food (MAFF) license. Under the terms of such a licence the shipper is required to see a copy of the Ministry permit before such strains can be supplied. Such licences are available in England and Wales from Ministry of Agriculture, Fisheries and Food, Room 340, Foss House, Kings Pool, 1-2 Peace Holme Green, York YO1 2PX and in Scotland from Plant Health Section, Agricultural Science Agency, East Craigs, Edinburgh EH12 8NJ.

Non-indigenous tree pathogens can only be supplied if the customer holds a current permit issued by The Forestry Commission: Forestry Commission Headquarters, 231 Corstorphine Road, Edinburgh EH12 7AP.

All shipments to Canada and the USA for plant pathogens must be accompanied by import mailing labels, without which entry of cultures to these countries is refused. Applications for these labels, stating the names of the organisms and the purpose for which they are required, should be made for Canada to the Chief of the Plant Protection Division, Agriculture Canada Science Division, Science Service Building, Ottawa, Ontario, Canada K1AS 0C5 and for the USA to USDA Agricultural Research Service, Plant Protection & Quarantine, Room 764, 6505 Belcrest Road, Hyattsville, Maryland 20782, USA.

Permit applications

USA

<http://www.aphis.usda.gov/ppq/permits/>

USA Regulated Pest list

<http://www.aphis.usda.gov/ppq/regpestlist/>

In the UK the Specified Animal Pathogens Order 1998 makes it an offence to possess or spread a listed animal pathogen within Great Britain without a license. It is supplemented by the Importation of Animal Pathogens Order 1980 which makes it an offence to import any animal pathogen, or potential or actual carrier, of an animal pathogen from a non-EC country, except under licence. Enquiries should be directed to the Animal Health Division of MAFF. The organisms covered by this order are indicated in table 1 by the symbol M1. Collection staff should note that both the Culture Collection and the customer must hold the appropriate licences. Orders will be refused where the customer is unable to provide a copy of the appropriate licence.

9. News from Countries and Regions and other News

News from countries and regions and PQSR Committee activities have been reported in the WFCC Newsletter 34 (annual report, pp. 12-16) and in the midterm report (see WFCC homepage).

In several cases of international cultures transport, especially to the USA, delay in delivery has been reported, due to customs controls on the background of European **BSE and FMD** problems. Senders of consignments were asked for detailed information regarding the contents of a consignment. The problem not only affects shipping to other countries but also within a country: in numerous cases, cultures recipients from the industrial area have been requesting certificates on the origin of all contents and growth compounds in a culture/ampoule.

The European CEN Standard EN 829 for packaging diagnostic samples or Risk Group 1 cultures will be proposed for withdrawal because it loses importance as it will be fully replaced by Packing Instruction PI 650 packages. Both are almost identical. EN 829 would represent an additional standard causing confusion. PI 650 packagings have a more international relevance as they are the only appropriate packagings mentioned by the UN Model Regulations and permitted for Category B cultures in the future (see 5.).

News taken from IATA DGR 2004, Limitations chapter:

AUG-03: "Infectious substances...are prohibited from entry to Australia without prior approval from Australian Health Authorities..."

BHG-02: "The Kingdom of Bahrain legislation expressly forbids the transport of...d) germs ...by aircraft..."

CAG-05: "Infectious substances are not permitted in the mail in Canada. ..."

CAG-10: "The entry of infectious substances affecting animals, UN 2900, into Canada is subject to the requirements of the Health of Animals Act (1990, c21) and prior approval from the Canadian Food Inspection Agency is required...."

CAG-11: "The entry of infectious substances affecting humans, UN 2814, into Canada is subject to the requirements of the Human Pathogens Importation Regulations (SOR/94-558)..."

DQG-03: "Infectious substances, including diagnostic specimens or biological products are not permitted in air mail to, from, within or over Fidji."

USG-13: it is referred to IATA DGR 2004, pp. 42.

VUG-02: "Infectious substances are prohibited from entry to Vanuatu without prior approval..."

There are several Operator (Airlines) variations, taken from DGR 2004, Packing Instruction PI 602 for infectious substances and summarised:

Air France, Alaska Airlines, China Airlines, Continental Airlines, Continental Micronesia, FEDEX, Hawaiian Airlines, Lan Chile Airlines, Lufthansa, US Airways.

In several countries, especially in Europe, PQSR Committee members have established specialised "job-specific" IATA dangerous goods training courses whereas such courses are known in the USA since years. Going together with almost not existing awareness on the laws, the establishment of such courses and to address the shippers of infectious substances seems very difficult.

With respect to bioterrorism/bio-weaponry discussions, WFCC's voice could be aired and WFCC's existence was brought into mind during the August 2003 Disarmament Experts Meeting in Geneva (invitation by the German Foreign Office) and during the first assembly meeting of a new European initiative: **NDA, New Defence Agenda** Bioterrorism Reporting Group in Brussels, June 2004 (www.newdefenceagenda.org). NDA is a neutral platform for discussing security policies.

10. Areas of Concern for Future Activities

- ! The Committee should compare different lists of Risk Group allocations of known microbial species and work towards their harmonisation where possible and should furthermore include newly described species. However, the majority of newly described microorganism species (bacteria and fungi) are not pathogens but other kinds of isolates whereas viruses dominate the number of new pathogens.
- ! The educational outreach aspect of Culture Collections in the context of distribution of dangerous organisms to third parties has been addressed by external personalities: this Committee could define possible ways of such an approach and offer suggestions to WFCC member collections how to establish courses, workshops, individual training and how to address the questions (publications, homepage information incl. FAQ pages).
- ! Repeating one topic under the Bioterrorism and Biosecurity Issues chapter, security will have to be tightened up even more, not only in Culture Collections, but in general. This will require consultations with the large microbiological societies on international (IUMS) and national levels in order to design a Code of Conduct. Such WFCC tasks would no doubt involve the PQSR Committee.
- ! Issue 7 of the Work Plan (see 1.) of the PQSR Committee has not yet been investigated during the past term of office and needs to be focused on: encompass ethics questions.
- ! World-wide gathering and distributing data on PQSR issues needs improvement.
- ! In anticipation of the coming transport deregulations, the PQSR Committee should not miss to prepare lists of microorganisms to be allocated to the new shipping Category B and procedures for implementation at the Culture Collections/BRCs. The coming deregulation is not just a simplification but needs recommendations for work flow plans.

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Prof. Lynne Sigler who has been an important companion during the negotiations at UNSCETDG in Geneva, especially for her enthusiasm and support.

All PQSR Committee members for their motivation to send prompt responses and input as we often had *ad hoc* Email discussions, questionnaires or urgent topics.

Ms. Linda Hume-Sastre for her proficient advice in helping us to become conversant with procedural questions in connection with our UNSCETDG negotiations.

Dr. Brian Tindall for using his excellent talent to lend wings to the liveliness of the world-wide scientific community so that WFCC was able to speak through the voices of the large microbiological societies:

Therefore, thanks are also extended to IUMS, FEMS, ASM, SGM and VAAM, especially those officers of these societies who responded promptly. The invaluable support by these large societies strengthened the WFCC PQSR Committee Proposal to the United Nations.

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Appendix

PROPOSAL BY THE WFCC, WORLD FEDERATION FOR CULTURE COLLECTIONS COMMITTEE ON POSTAL, QUARANTINE AND SAFETY REGULATIONS

TO BE OFFERED TO THE UNITED NATIONS SUB-COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS

PROPOSAL FOR A MODIFICATION OF SHIPPING REGULATIONS FOR BIOLOGICAL MATERIALS CLASSIFIED IN RISK GROUP 2/CATEGORY B CULTURES

BACKGROUND

The World Health Organisation Risk Group definition scheme sets the basis for the Risk Group allocation of all kinds of microorganisms and is intended to protect personnel working with biological agents in the laboratory. Classification of microorganisms with respect to health and safety at the work place was the basic concern.

Considering the infectivity and pathogenicity of Risk Group 2 organisms and the availability of preventive and therapeutic measures the risk is low for employees and the public.

Microorganisms classified in Risk Group 2 by the European Council Directive 2000/54/EEC of September 2000 (amending 90/679/EEC) include a high number of described species known to live as commensals e.g. on the human oral mucosa or which are generally widespread in the environment. There are countless examples for rather harmless organisms of Risk Group 2 which may be regarded as opportunistic or low grade pathogens being documented only in nosocomial infections. Without doubt, organisms meeting the definition of the new Division 6.2 Category B for shipping purposes fall into the Risk Group 2.

ROLE OF THE WFCC

Correct packaging and shipping of biological materials is a matter of justified concern. For many years this kind of international bio-legislation has been one of the main topics of discussion for the WFCC (World Federation for Culture Collections) Committee dedicated to questions and international or regional developments on Postal, Quarantine and Safety Regulations. The WFCC, founded in 1963, is a multidisciplinary Commission of the International Union of Biological Sciences (IUBS) and since the separation of the International Union of Microbiological Societies (IUMS) from IUBS in 1979 has operated as an inter-union Commission. It seeks to promote and foster activities that support the interests of Biological Resource Centres and the scientific community in the ex situ conservation and utilisation of the biological diversity. The WFCC represents over 470 member collections from 62 countries who have over 1700 staff including some of the worlds leading scientists and has published guidelines for the establishment and operation of Biological Resource Centres and has several standing committees. The Committee on Postal, Quarantine and Safety Regulations (PQSR) has contributed considerably to the distribution of information and consequently to a raised awareness in this area and functions as an information forum. There are currently eleven members of different nations in this Committee, all are experienced scientists working in renowned culture collections/biological resource centres. They have hands on practical knowledge of the implementation of safety measures and bio-legislation. WFCC and its Committees present information via <http://www.wfcc.info>.

WFCC PROPOSAL

The WFCC PQSR Committee proposes a modification of the UN Model Regulations with respect to classified Risk Group 2 cultures transported for the purposes of scientific laboratory work as follows:

“2.6.3.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373.

2.6.3.2.2.2.1 Cultures, as defined in 2.6.3.1.3, that contain Category B infectious substances shall be assigned to UN 2814 or UN 2900, as appropriate, except that substances classified for the purposes of laboratory work as Risk Group 2, if they are to be transported, may be offered for transport as Category B, UN 3373.”

We suggest to use the Proper Shipping Name “Infectious substance, Category B” (or vice versa).

As a precondition of adopting this WFCC proposal, it is important to make a realistic comparison of potential risk during laboratory work and during transport. Both situations should be carefully balanced when the regulations are reviewed as it is apparent that the risk associated with safely packaged cultures in transit is significantly lower than the risk when working with them. It is also a fact that a perceived risk in contrast to a real risk plays a role as an emotional aspect when transporting infectious substances. According to international rules, laboratory cultures have to be classified within the WHO Risk Group definition system based on sound scientific knowledge and description of each organism. The definition of Category A: “An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals” definitely excludes those organisms classified in Risk Group 2: “Organisms classified in Risk Group 2 can cause diseases among employees. Considering the infectivity, pathogenicity and the availability of preventive and therapeutic measures the risk is low for employees and the public.” Exclusively the classified characterised Risk Group 2 organisms are subject of this proposal.

If a Risk Group 2/Category B organism is properly packed and offered for transport in a high quality UN packaging system according to PI 650 (for diagnostic/clinical specimens, UN 3373), such a consignment is as safe as under PI 602 (for infectious substances meeting the definition of Category A). Shipments containing known species are in most cases not more dangerous than shipments containing diagnostic specimens with an unknown pathogenic potential. Furthermore, scientists or Biological Resource Centres are often exchanging small amounts of freeze-dried microorganisms being in a physiological inactive form. They usually bear *a priori* a lower risk than diagnostic specimens. The former are often laboratory derivatives which need a preculturing step, the latter are natural cultures directly isolated from patients.

The WFCC Committee endorses such a new model for international shipping of microorganisms in which realistic simplifications, especially concerning administrative expenditure, will lead to enhancing and strengthening the willingness to adhere to the laws while the transport itself would by no means become less safe. In contrast, the current complicated and extraordinarily expensive shipping-conditions for Risk Group 2 organisms result in serious impediments to microbiological research. Shippers are often not adhering to any regulation and use undeclared letter mail.

Transport of microorganisms falling under the Risk Group 3 or 4 definitions, is not subject to the discussions in this proposal.

On behalf of the WFCC Committee on Postal, Quarantine and Safety Regulations,

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April 2004



ST/SG/AC.10/C.3/INF/
19 April 2004

ORIGINAL: ENGLISH

**COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**

Sub-Committee of Experts on the
Transport of Dangerous Goods

Twenty-fifth session, 5-14 July 2004
Item 6 of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

REVISIONS TO ST/SG/AC.10/C.3/2004/51

Transmitted by the World Federation for Culture Collections (WFCC)

Background

The WFCC recognizes that the proposal submitted in ST/SG/AC.10/C3/2004/51 may not have clearly articulated the change to the UN Model Regulations that the WFCC is proposing.

Consequently, it is hoped that this revision will clarify the WFCC's intent.

The WFCC recognizes that laboratories in hospitals, diagnostic and research facilities handle samples of human, animal or other biological material and cultures derived from them. These are classified according to the World Health Organization's Risk Group classification criteria. The Risk Group criteria are based on the risk posed in the laboratory and determine biosafety levels, practices and equipment for laboratory work. If samples or cultures are to be transported then the laboratory, hospital or other facility must comply with transport requirements including classification and packaging. In order to better reflect the risks during transport, the UN Model Regulations have moved away from the concept of Risk Groups. The UN Model Regulations require cultures classified in Category B to be transported as Category A under UN numbers UN2814 or UN2900. However, if shipment of such cultures is intended for diagnostic or clinical purposes transport as UN3373 is permitted.

Category A includes infectious substances which are transported in a form that, when exposure to them occurs, are capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Microorganisms included in Category A are listed in UN Model Regulations 2.6.3.2.2.1. The category includes microorganisms which may be classified in different Risk Groups in different regions or countries, but primarily includes Risk Group 3 or 4 organisms.

Category B includes infectious substances which do not meet the criteria for inclusion in Category A. However, such cultures are to be transported as Category A under UN numbers UN2814 or UN2900 if intended for investigational scientific laboratory purposes.

WFCC proposal

In ST/SG/AC.10/C3/2004/51 WFCC stated that cultures of Category B Risk Group 2 microorganisms pose a low risk for employees in laboratory work and for the public for transport purposes given their low level of infectivity and pathogenicity and the availability of preventive and therapeutic measures. See Risk Group 2 definitions by several international Authorities below.

Consequently, the WFCC believes that cultures of Category B Risk Group 2 substances for laboratory or investigational work can be safely transported as Category B under UN3373.

The WFCC proposes modifications to the UN Model Regulations with respect to the transport of Risk Group 2 cultures as follows:

- * that 2.6.3.1.3, the cultures (laboratory stocks) definition be re-worded as follows:

“Cultures (laboratory stocks) are the result of a process by which pathogens are amplified or propagated in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic, clinical and investigational purposes like laboratory assay, quality control or reference purposes”

- * that, given the low risk such organisms pose even in cultured form, they can be safely transported as Category B, UN 3373, in packaging that is in compliance with P650;

- * that 2.6.3.2.2.2, the Category B definition, be re-worded as follows:

“2.6.3.2.2.2 Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373. Cultures, as defined in 2.6.3.1.3, that contain Category B infectious substances shall be assigned to UN 2814 or UN 2900, as appropriate, except that substances classified for the purposes of laboratory work as Risk Group 2, may be transported as Category B, UN 3373.”

Note: The proper shipping name of UN 3373 should be “DIAGNOSTIC SPECIMENS” or “CLINICAL SPECIMENS” or “BIOLOGICAL CULTURES, Category B”.

As stated in ST/SG/AC.10/C3/2004/51, it is important to make a realistic comparison of potential risk during laboratory work and during transport. Both situations should be carefully balanced when the regulations are reviewed as it is apparent that the risk associated with safely packaged cultures in transport is significantly lower than the risk when working with them. The WFCC recognizes that a perceived risk in contrast to a real risk plays a role as an emotional aspect when transporting infectious substances.

The members of WFCC endorse the view that a Risk Group 2 culture marked and packaged in accordance with P650 is as safe for transport as compliance with the requirements for Category A substances.

Risk Group 2 Definitions by different International Authorities:

European Economic Community:

“Group 2 biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available.”

NIH Guidelines:

“Risk Group 2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.”

Canadian Laboratory Biosafety Guidelines:

“Risk Group 2 (moderate individual risk, limited community risk) A pathogen that can cause human or animal disease but under normal circumstances, is unlikely to be a serious hazard to healthy laboratory workers, the community, livestock, or the environment. Laboratory exposures rarely cause infection leading to serious disease, effective treatment and preventive measures are available and the risk of spread is limited.”

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories:

“Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.”

WHO Laboratory Biosafety Manual:

Risk Group 2 (moderate individual risk, low community risk)

A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.